

Application # 09/732,838
RCE Preliminary Amendment dated January 10, 2005
Reply to Final Office Action dated August 10, 2004

PATENT
P-5093

REMARKS

Claim 47 has been amended to incorporate the limitations of original Claim 1, support for this amendment can also be found at page 10 line 3 to page 11 line 3 of applicant's specification.

Claims 47-56 are pending in the application.

Claim Rejections – 35 USC § 103

Claims 47-51 are rejected under 35 U.S.C. § 103(a) as being patentable over U.S. Patent application No. 4,514,508 to Hirschfeld. ("Hirschfeld") in view of Ueda et al ("Ueda") (Journal of Clinical Microbiology, vol. 36(2), Feb. 1998, pp 340-344.

The claims are rejected for the reasons of record in the previous office action.

This rejection is respectfully traversed in view of the amendment.

Of the claims rejected, Claim 47, is independent, with the remaining claims dependent thereon.

Amended Claim 47 now recites among other things:

(a) an analytical test device having a plurality of wells, wherein the wells do not communicate with each other; and wherein each well comprises:

a filter stack, the filter stack comprising:

(i) a porous membrane having an upper surface and a lower surface; and

(ii) an absorbent material,

wherein said lower surface of said porous membrane and said absorbent material are in physical contact and in fluid communication, and

wherein upon contact of a biological fluid sample suspected of containing one or both of the Influenza A viral antigens and the Influenza B viral antigens with said porous membrane, said fluid is able to flow through said membrane into said absorbent material, such that at least a portion of said viral antigens present in said biological fluid sample bind to said porous membrane;

The applicant's invention defined by Claims 47-51 is neither taught nor rendered obvious by the cited references. Hirschfeld has no disclosure or suggestion of providing in each well a filter stack having a porous membrane and an absorbent material, wherein the lower surface of the membrane and the absorbent material are in physical contact and in fluid communication.

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In, particular, use of the claimed invention involves bringing a liquid sample into contact with the filter stack, where the sample is able to flow through the porous membrane (and then onto absorbent material) such that one or more Influenza antigens present in the sample bind to the membrane (without the need for a capture antibody on the membrane surface). The device thus utilizes a dynamic incubation. Antigen captured on the membrane may be detected, for example, by introducing the recited detection reagents, followed by the signal-generating reagent.

By contrast, Hirschfeld utilizes a static incubation without a porous membrane or absorbent material. Specifically Hirschfeld discloses a sandwich immunoassay using a multiwell microtiter plate in which the antibody has been applied to the surface of the well and then covered with a coating compound. The fluid sample is then added to each well for a static incubation, in which the liquid sample resides in the well, during which the antigens may combine with the antibody on the surface of the well. The fluid sample has to then be removed out of the well, before introduction of a detection agent.

Thus, the Hirschfeld device would have to be completely redeveloped to resemble the invention defined by claims 47-51. No such redevelopment is suggested either by Hirschfeld or Ueda.

Ueda was cited solely for teaching the use of 2 monoclonal antibodies for the detection of Influenza A and Influenza B. Thus, Ueda does not overcome the deficiencies of Hirschfeld as set forth above.

For this reason applicants submit that independent Claim 47, dependent Claims 48-51 are not rendered obvious by the combination of Hirschfeld with the Ueda reference.

Claims 52-53 are rejected under 35 U.S.C. § 103(a) as being patentable over Hirschfeld in view of Ueda as applied to claims 47-51 and 54 above, and further in view of U.S. Patent application No. 5,494,801 to Bogart et al. ("Bogart").

This rejection is respectfully traversed in view of the amendment.

Bogart is relied on only for the use of mucolytic agents to extract antigens from a body fluid, and does not overcome the deficiencies of Hirschfeld as explained above and Claim 52, being dependent on claim 47, and Claim 53 being dependent on claim 52, are patentable over the cited references.

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Claims 55-56 are rejected under 35 U.S.C. § 103(a) as being patentable over Hirschfeld in view of Ueda as applied to claims 47-51 and 54 above, and further in view of U.S. Patent application No. 5,279,935 to Nyez. ("Nyez").

This rejection is respectfully traversed in view of the amendment.

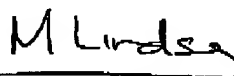
Nyez is relied on only for the use of citric acid to deactivate any endogenous alkaline phosphatase that may be present to the enzymatic detection process, and does not overcome the deficiencies of Hirschfeld as explained above and Claim 55, being dependent on claim 47, and Claim 56 being dependent on claim 55, are patentable over the cited references.

In view of these remarks, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's agent at the telephone number set forth below.

Respectfully submitted,



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